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09/993,736	11/14/2001	Richard Philpott	56066/45858	9454
21874	7590	10/20/2003	EXAMINER	
EDWARDS & ANGELL, LLP P.O. BOX 9169 BOSTON, MA 02209			GOLDBERG, JEANINE ANNE	
			ART UNIT	PAPER NUMBER
			1634	

DATE MAILED: 10/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/993,736

Applicant(s)

PHILPOTT ET AL.

Examiner

Jeanine A Goldberg

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 2-4, 7-27, 29-32 and 35-43 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2-4, 7-27, 29-32 and 35-43 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

### **DETAILED ACTION**

1. This action is in response to the papers filed June 24, 2003. Currently, claims 2-4, 7-27, 29-32, 35-43 are pending.
2. All arguments have been thoroughly reviewed but are deemed non-persuasive for the reasons which follow. This action is made FINAL.
3. Any objections and rejections not reiterated below are hereby withdrawn in view of the amendments to the claims or applicant's arguments.
4. This action contains new grounds of rejection necessitated by amendment.

### ***New Grounds of Rejection Necessitated by Amendment***

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 2-4, 7, 9-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A1) Claims 2-4, 7, 9-10 are indefinite over the recitation "the solid medium" because it is unclear which of the two solid mediums set forth in the claims is being referred to in step d.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 2, 4, 7, 10, 35-36, 38-40, 42-43 are rejected under 35 U.S.C. 102(e) as being anticipated by Robertson (US Pat. 6,153,104, November 28, 2000).

Robertson teaches a method of body fluid separation. The method uses a device comprising a chamber, a cooperating filter, a second chamber, where the first and second chamber has a connection to vacuum with filters on each side and a removable closure in the form of end caps. As seen in Figure 1 the device is provided. Robertson teaches that the invention provides equipment of notable simplicity and relatively low cost with method steps well within the capabilities of junior members of laboratory staff, to enable separation of a body fluid into various of its component (col. 1, lines 30-35). Robertson teaches obtaining a biological sample, namely a whole blood sample (limitations of 35a). The biological sample is in a suspension comprising genetic material, as whole blood is comprised of plasma, serum and cells (limitations of

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Claim 35b, 38). An apparatus comprising a chamber, two solid mediums, a vacuum means where the second filter has a composition sorbed thereon. The matrix may comprise water, water/isotonic saline or cell detergent (col. 2, lines 40-50)(limitations of Claim 35c, 36). The whole blood sample is applied to one side of a filter, vacuum is applied to the opposite side of the filter to draw the whole blood sample there through and separate the plasma and red cell content of the blood from the leukocyte cell content, leaving the leukocyte content trapped in the filter (col. 2, lines 30-50)(limitations of Claim 35d, e). Following lysing, the chamber is inverted and the saline is applied to the opposite side of the filter to wash out the cell contents of the leukocyte cells from the filter into an appropriate receptacle from where the DNA content is removed. Robertson teaches that to gather the cell contents of the leukocyte cells, it is most desirable that a filter membrane is provided to isolate the DNA content of the cells from other cell debris washed from the filter (col. 4, lines 60-65)(limitations of Claim 10, 42-43). Thus the genetic material is retained on the second solid medium. Robertson teaches that once the cells have been isolated, probes and further techniques may be used for analyzing the genetic material (col. 5)(limitations of Claim 40).

7. Claims 2, 7, 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Alberts (Molecular Biology of The Cell. 3<sup>rd</sup> Edition, 1994).

Alberts teaches a method of analyzing cells by DNA cloning. DNA fragments are inserted into the purified DNA genome of a self-replicating genetic element- generally a virus or a plasmid, upstream processing of a biological sample (page 308). The

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bacteria is plated out on medium containing antibiotic and let to grow (page 309).

Culturing dishes containing growing bacterial colonies are blotted with a piece of filter paper (second solid medium). The paper is treated with alkali to disrupt the cells and incubated with labeled DNA probe. As seen in Figure 7-26, two solid mediums are used which allow for genetic analysis. Thus, since Alberts teaches every limitation of the claims, Alberts anticipates the claimed invention.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 3, 8-9, 16, 19, 21, 29-32, 37, 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Robertson (US Pat. 6,153,104, November 28, 2000) in view of Burgoyne (US Pat. 5,807,527, September 1998).

Robertson teaches a method of body fluid separation. The method uses a device comprising a chamber, a cooperating filter, a second chamber, where the first and second chamber has a connection to vacuum with filters on each side and a removable closure in the form of end caps. As seen in Figure 1 the device is provided. Robertson teaches that the invention provides equipment of notable simplicity and relatively low cost with method steps well within the capabilities of junior members of laboratory staff, to enable separation of a body fluid into various of its component (col. 1, lines 30-35). Robertson teaches obtaining a biological sample, namely a whole blood sample (limitations of 35a). The biological sample is in a suspension comprising genetic material, as whole blood is comprised of plasma, serum and cells (limitations of Claim 35b, 38). An apparatus comprising a chamber, two solid mediums, a vacuum means where the second filter has a composition sorbed thereon. The matrix may comprise water, water/isotonic saline or cell detergent (col. 2, lines 40-50)(limitations of Claim 35c, 36). The whole blood sample is applied to one side of a filter, vacuum is applied to the opposite side of the filter to draw the whole blood sample there through and separate the plasma and red cell content of the blood from the leukocyte cell content, leaving the leukocyte content trapped in the filter (col. 2, lines 30-50)(limitations of Claim 35d, e). Following lysing, the chamber is inverted and the saline is applied to the opposite side of the filter to wash out the cell contents of the leukocyte cells from the

filter into an appropriate receptacle from whether the DNA content is removed.

Robertson teaches that to gather the cell contents of the leukocyte cells, it is most desirable that a filter membrane is provided to isolate the DNA content of the cells from other cell debris washed from the filter (col. 4, lines 60-65)(limitations of Claim 10, 42-43). Thus the genetic material is retained on the second solid medium. Robertson teaches that once the cells have been isolated, probes and further techniques may be used for analyzing the genetic material (col. 5)(limitations of Claim 40).

Robertson does not specifically teach using the preserving means which contains a weak base, a chelating agent or an anionic surfactant or detergent.

However, Burgoyne teaches a method of storage of DNA using solid medium having a compound which protects against degradation of DNA incorporated into or absorbed on the matrix, and for recovery of DNA or in situ use of DNA (abstract). Blood dried onto filter paper is a proven alternative and has been shown that DNA can be extracted and isolated from dried blood spots in a form and in sufficient quantities for use in DNA analysis (col. 1, lines 60-65). Burgoyne teaches that the solid matrix may comprise a solid support such as an absorbent cellulose-based paper or a micromesh of synthetic plastics material. Moreover, Burgoyne teaches that the solid medium comprises a composition comprising a weak base, a chelating agent and an anionic surfactant or detergent (col. 2, lines 60-64)(limitations of Claim 3). DNA on filter paper specially treated in accordance with this invention was purified in situ, then subjected to the polymerase chain reaction (col. 4, lines 37-30). Burgoyne teaches that treated paper was much more efficient than untreated paper. Treated paper gave recoveries of



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approximately 100% where as untreated paper only has about 10% recovery (col. 6, lines 8-10). Burgoyne teaches that exon 2 of the nRAs protooncogene and male specific Y chromosome repeat, were genotyped (limitation of Claim 2). Burgoyne teaches that DNA may be stored on the solid matrix having a composition thereon are suited for performance under automated conditions. Burgoyne teaches that the means of storage may be established for long term storage and may be kept in orderly, low-volume files (col. 4-5).

There, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Robertson to use the composition taught by Burgoyne for lysing cells. Burgoyne teaches the benefits of using the solid support for storage of DNA for long periods of time. The benefits of the storage of the DNA upon the solid matrix additional includes the low-volume files as compared to liquid blood samples which require more care. Therefore, the ordinary artisan would have been motivated to have purified leukocytes from blood using the particular composition taught by Burgoyne for the expected benefit of diagnostic importance.

### ***Conclusion***

**10. No claims allowable over the art.**

**11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP**

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jeanine Goldberg whose telephone number is (703) 306-5817. The examiner can normally be reached Monday-Friday from 8:00 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax number for this Group is (703) 305- 3014.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

*J. Goldberg*  
Jeanine Goldberg  
October 16, 2003

JEHANNE SOUAYA  
PATENT EXAMINER  
*Primary*  
*Jehanne Souaya*  
*10/16/03*